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10/580,458

05/24/2006

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,458	<b>Applicant(s)</b> VAINCHENKER ET AL.	
	<b>Examiner</b> SHERIDAN SWOPE	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 10-23, 27 and 32-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9, 24-26, 28-31 and 42 is/are rejected.
- 7) ☒ Claim(s) 1-4, 8, 9, 24-26, 28-31 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0506:0806:0208:0708</u> .                                     | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' election with traverse of Invention I, in their response of June 20, 2008, is acknowledged. Applicants' traversal is based on the argument that the claims comprise the special technical feature of all being related to JAK2 having a V617F mutation, which was unknown in the art (see 11/943,359). This argument is not found to be persuasive for the following reasons. First, while the technical feature linking the claims of Group I is that they all relate to proteins comprising aV617F mutation, said feature is not a special technical feature because such proteins were known in the art (Kawamura et al, 1994). Second, as explained in the prior action, the products and methods of Groups II-VIII are not encompassed by said technical feature because said products do not share a common structure and function with the products of Group I, while said methods do not share the same modes of operation, functions, or effects of the methods of Group I. The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-42 are pending. Claims 5-7, 10-23, 27, and 32-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 1-4, 8, 9, 24-26, 28-31, and 42 are hereby examined.

### ***Priority***

The priority date granted for the invention of Claims 1-4, 8, 24-26, 28-31, and 42 is October 27, 2004, the filing date of FR 0411480, which disclosed the elected invention. The priority date granted for the invention of Claim 9 is October 26, 2005, the filing date of PCT/EP05/55586, which disclosed the elected invention, including SEQ ID NO: 15-28.

***Abstract***

The abstract is objected to because there are two versions, both filed on the same date. It is unclear which version is to be used.

***Drawings-Objections***

Figure 1 is objected to because the legend thereto states it is a representation of the role of JAK2 in PV; however, the term PV fails to occur in said figure.

Figure 5 is objected because the three panels are not labeled.

Figure 8 is objected to for disclosing sequences that are not identified by SEQ ID NOs:.

Figures 9 and 10 are objected to because the lanes are not labeled or explained.

***Specification-Objections***

The legend to Figures 2, 3, 5, 9, and 10 are objected to because they fail to clearly explain the data of the figures. The legend to Figure 5 is also objected because it fails to explain the three panels.

The specification is objected to for containing hyperlinks. USPTO policy does not permit the USPTO, i.e, via an issued patent, to refer to any commercial sites, since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not to be included in a patent application. (MPEP 608.01) The specification should be carefully checked and all URLs removed.

***Claims-Objections***

Claims 1-4, 8, 9, 24-26, 28-31, and 42 are objected to for lacking an article at the beginning; for example, “An isolated JAK2” for Claim 1.

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Claim 24 is objected to for “in a tumor comprising one or more primers...”, which would be better stated as “in a tumor, wherein the kit comprises one or more primers...”.

Claim 25 is objected to for “Kit for determining...”, which would be better stated as “Kit, for determining...”.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-4, 28-31, and 42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The polynucleotide of Claim 2, the vector of Claim 3, the mammalian cell of Claim 4, and the siRNAs of Claims 28-31 and 42 are likely to occur in nature, therefore the recited subject matter fails to show the “hand of man”. It is suggested that the claims be amended to recite “isolated” or “recombinant”.

### ***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8, 9, 24-26, 28-31, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claims 1-4, 8, 9, 24-26, 28-31, and 42, the phrase JAK2 renders the claims indefinite. The specification discloses that:

“JAK2 belongs to the family of Janus Kinases (JAKs) which group together several intracytoplasmic tyrosine kinases: JAK1, JAK2, JAK3 and TYK2. The JAK proteins are involved in

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the intracellular signalling of numerous membrane receptors which have no intrinsic tyrosine kinase activity...”

Said disclosure is not sufficient to define the function of “JAK2”. The skilled artisan would not know the metes and bounds of the recited invention.

For Claim 1, the phrase “comprises a mutation on amino acid 617” in combination with “sequence is shown in SEQ ID NO: 1” renders the claim indefinite. It is unclear whether said phrase means the JAK2 kinase is (i) the sequence of SEQ ID NO: 1, (ii) the sequence of SEQ ID NO: 1 with any residue at 617 except valine, or (iii) any JAK2 protein having at least a mutation at residue 617. The skilled artisan would not know the metes and bounds of the recited invention. Claims 2-4, 8, 9, 24-26, 28-31, and 42, as dependent from Claim 1, are indefinite for the same reason. Taking the broadest reasonable interpretation, for purposes of examination, it is assumed that the recited subject matter encompasses any “JAK2” protein having at least a mutation at residue 617.

For Claim 1, the phrase “mutation on amino acid 617, more particularly the V617F mutation” renders the claim indefinite. Recitation of a broad scope (any mutation at 617) followed by recitation, in the same claim, of a narrow scope (V617F) encompassed by the broad scope renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claims 2-4, 8, 9, 24-26, 28-31, and 42, as dependent from Claim 1, are indefinite for the same reason. For purposes of examination, it is assumed that the recited subject matter encompasses any “JAK2” protein having any mutation of the valine at residue 617.

For Claim 1, the phrase “similar sequence” renders the claim indefinite. The term “similar” is a relative term which renders the claim indefinite. The term “similar” is not defined

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by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-4, 8, 9, 24-26, 28-31, and 42, as dependent from Claim 1, are indefinite for the same reason.

For Claim 2, the phrase “encoding the JAK2 V617F variant..., in particular SEQ ID NO: 2” renders the claim indefinite. Recitation of a broad scope (any polynucleotide encoding the JAK2 V617F variant) followed by recitation, in the same claim, of a narrow scope (SEQ ID NO: 2) encompassed by the broad scope renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claim 3, as dependent from Claim 2, is indefinite for the same reason. For purposes of examination, it is assumed that the recited subject matter encompasses any polynucleotide encoding the JAK2 V617F variant of SEQ ID NO: 1.

For Claim 2, the phrase “position 1849” renders the claim indefinite. Recitation of a specific residue by position number, without reference to a specific sequence comprising said residue at said position number renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claim 3, as dependent from Claim 2, is indefinite for the same reason. It is noted that, because the identities of the sequences recited in Claims 2 and 3 are unclear, said sequences could not be searched. Any subsequent rejection based on clarification of the recited subject matter will not be considered new grounds for rejection.

For Claim 3, the phrase “efficient promoter” renders the claim indefinite. The term “efficient” is a relative term which renders the claim indefinite. How efficient must a promoter be to be encompassed by the claims? The term “efficient” is not defined by the claim, the

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specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

For Claims 8 and 9, the phrase “probes and primers” renders the claim indefinite. It is unclear whether said phrase means “a probe or primer”, “a pair of probes or primers”, “one or more probes or primers”, or “a plurality of probes and primer”. The skilled artisan would not know the metes and bounds of the recited invention. Claims 24-26, as dependent from Claim 8, are indefinite for the same reason. For purposes of examination, it is assumed that “probes and primers” means “a plurality of probes and primer”.

For Claim 8, the phrase “position 1849” renders the claim indefinite. SEQ ID NO: 3 and 4 are 554 nucleotides and 94 nucleotides, respectively. As explained above, recitation of a specific residue by position number, without reference to a specific sequence comprising said residue at said position number renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claims 9 and 24-26, as dependent from Claim 8, are indefinite for the same reason. It is noted that, because the identities of the sequences recited in Claims 8, 9, and 24-26 are unclear, said sequences could not be searched. Any subsequent rejection based on clarification of the recited subject matter will not be considered new grounds for rejection.

For Claims 24, 25, and 29, the phrase “G1849T” or “t<sup>1849</sup>” renders the claims indefinite. As explained above, recitation of a specific residue by position number, without reference to a specific sequence comprising said residue at said position number renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claim 26, as dependent from Claim 24, is indefinite for the same reason. It is noted that, because the



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identities of the sequences recited in Claims 24-26 and 29 are unclear, said sequences could not be searched. Any subsequent rejection based on clarification of the recited subject matter will not be considered new grounds for rejection.

For Claim 25, the phrase “suffering from Vaquez polyglobulia or from any other myeloproliferative disorder...” renders the claim indefinite. Recitation of a broad scope (any myeloproliferative disorder) and also recitation, in the same claim, of a narrow scope (Vaquez polyglobulia) encompassed by the broad scope renders the claim indefinite. In addition, for Claim 25, the phrase “suffering from ... any other myeloproliferative disorder ..., in particular, erythrocytoses, hyperleukocytoses, thrombocytoses and myelofibroses” also renders the claim indefinite. Recitation of a broad scope (any myeloproliferative disorder) and also recitation, in the same claim, of a narrow scope (erythrocytoses, hyperleukocytoses, thrombocytoses and myelofibroses) encompassed by the broad scope renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that the recited subject matter encompasses myeloproliferative disorder.

For Claim 28, the phrase “reducing by more than 50%, or more than 95%” renders the claim indefinite. Recitation of a broad scope (reducing by more than 50%) followed by recitation, in the same claim, of a narrow scope (reducing by... more than 95%) encompassed by the broad scope renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. Claims 29-31, as dependent from Claim 28, are indefinite for the same reason. For purposes of examination, it is assumed that the recited subject matter encompasses any siRNA capable of reducing expression by more than 50%.

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For Claim 29, the phrase “19 to 25 nucleotides, preferably 19 nucleotides” renders the claim indefinite. Recitation of a broad scope (19 to 25 nucleotides) followed by recitation, in the same claim, of a narrow scope (19 nucleotides) encompassed by the broad scope renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that the recited subject matter encompasses “19 to 25 nucleotides”.

For Claim 30, the phrase “reduction of more than 80% or 95%” renders the claim indefinite. Recitation of a broad scope (reduction of more than 80%) followed by recitation, in the same claim, of a narrow scope (reduction of more than ...95%) encompassed by the broad scope renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that the recited subject matter encompasses “reduction of more than 80%”.

For Claim 30, the phrase “reduction of less than 25% or 5%” renders the claim indefinite. Recitation of a broad scope (reduction of less than 25%) followed by recitation, in the same claim, of a narrow scope (reduction of less than ...5%) encompassed by the broad scope renders the claim indefinite. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that the recited subject matter encompasses “reduction of less than 25%”.

Claim 31 is rendered indefinite by improper Markush language. An “and” should be inserted between SEQ ID NO: 30 and 31 in the list.

Claims 3, 4, 9, 26, and 29-31 are indefinite for improper antecedent usage as follows.

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For Claim 3, “the sequence” lacks antecedent basis and should be corrected to “the nucleotide sequence”.

For Claim 4, “the recombinant JAK2...” lacks antecedent basis.

For Claim 9, the phrase “Probes or primers according to claim 8” should be corrected to “The probes or primers according to claim 8”.

For Claim 26, “the hybridization step” lacks antecedent basis.

For Claim 26, “the marker” lacks antecedent basis.

For Claim 26, the phrase “Kit according to claim 24” should be corrected to “The kit according to claim 24”.

For Claims 29-31, the phrase “siRNA according to claim 28” should be corrected to “The siRNA according to claim 28”.

### ***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### **Enablement**

Claims 1-4, 8, 9, 24-26, 28-31, and 42 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a probe that recognizes the V617F mutation in SEQ ID NO: 1, or an encoding nucleotide sequence, does not reasonably provide enablement for any protein having a V617F mutation, wherein the protein has any structure and any or no function, encoding polynucleotides, or any probes, primers, or siRNAs thereof. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1, 4, and 42 are so broad as to encompass any protein having at least a mutation at residue 617 or any protein in another mammal that is “similar” to SEQ ID NO: 1, wherein the protein has any or no activity. The specification fails to enable the skilled artisan to make and use the subject matter of Claims 2, 3, 8, 9, 24-26, and 29 because the metes and bounds of said subject matter is unclear. Claims 28 and 30 are so broad as to encompass any siRNA molecule capable of reducing expression of any polynucleotide encoding SEQ ID NO: 1 in any cell.

The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides and polynucleotides broadly encompassed by the claim. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a

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protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims. Furthermore, the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable (Galys et al, 1993; Whisstock et al, 2003). In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of Claims 1, 4, and 42, which encompasses all "JAK2" proteins having at least a mutation at residue 617 or any "JAK2" protein in another mammal that is "similar" to SEQ ID NO: 1, wherein the "JAK2" protein has any or no activity. The specification does not support the scope of Claims 2, 3, 8, 9, 24-26, and 29 because the metes and bounds of said claims is unclear. The specification does not support the broad scope of Claims 28 and 30, which encompasses all siRNA molecules capable of reducing expression of any polynucleotide encoding SEQ ID NO: 1 in any cell. The specification does not support the broad scope of Claims 1-4, 8, 9, 24-26, and 28-31 because the specification does not establish: (A) the function of the protein of SEQ ID NO: 1, except that

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residue V617F thereof is a marker for PV; (B) the function of all “JAK2” proteins having at least a mutation at residue 617 or any “JAK2” protein in another mammal that is “similar” to SEQ ID NO: 1; (C) regions of any “JAK2” protein structure which may, or may not, be modified without affecting the desired activity; (D) the general tolerance of the desired activity to modification and extent of such tolerance; (E) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; (F) a use for the polynucleotide of SEQ ID NO: 2, except that the mutation G1849T is a marker for PV; (G) the metes and bounds of the subject matter of Claims 1-4, 8, 9, 24-26, and 28-31; (H) a use for reducing the expression of SEQ ID NO: 2 and the siRNA molecules capable of affecting said reducing; and (I) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful for attaining the desired utility.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of “JAK2” polypeptides, variants thereof, encoding polynucleotides, and probes, primers, and siRNA molecules thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

### **Written Description**

Claims 1, 4, and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of proteins having at least a mutation at residue 617 or any protein in another mammal that is “similar” to SEQ ID NO: 1, wherein the protein has any or no activity. The specification teaches the structure of only a single representative species of such proteins. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having at least a mutation at residue 617 or any protein in another mammal that is “similar” to SEQ ID NO: 1, wherein the protein has any or no activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Because the metes and bounds of Claims 2, 3, 8, 9, 24-26, and 29 is unclear, it is also unclear whether Applicants were in full possession of the claimed subject matter.

Claims 28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of siRNA molecules capable of reducing expression of any polynucleotide encoding SEQ ID NO: 1 in any cell. The specification teaches the structure of only a three representative species of such siRNA

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molecules, which are capable of reducing expression of a polynucleotide encoding SEQ ID NO: 1 in a single cell type (Figs 8-9). Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being a siRNA molecule capable of reducing expression of any polynucleotide encoding SEQ ID NO: 1 in any cell. Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawamura et al, 1994. Kawamura et al teach a JAK kinase (Fig. 1), wherein the residue, corresponding to V617 in SEQ ID NO: 1 herein, is a methionine residue. Kawamura et al further teach a mammalian cell expressing said kinase (Fig. 2). Therefore, Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawamura et al, 1994.

***Allowable Subject Matter***

No claims are allowable.



### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-092834. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652